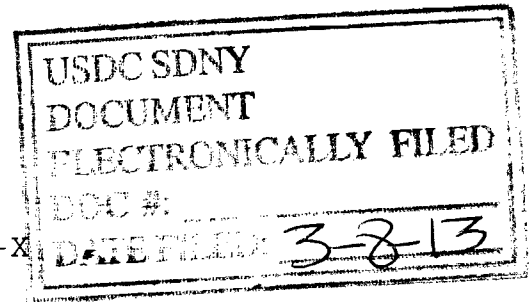


UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK



-----X-----  
CHRISTEL BILLHOFER, On Behalf of  
Herself and All Others Similarly  
Situating,

07 Civ. 9920

Plaintiffs,

OPINION

-against-

FLAMEL TECHNOLOGIES, S.A., et al.,

Defendants.

-----X-----  
A P P E A R A N C E S:

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**Sweet, D.J.**

Defendants Flamel Technologies, S.A. ("Flamel") and Stephen H. Willard ("Willard") (collectively the "Flamel Defendants") have moved pursuant to Rule 56 of the Federal Rules of Civil Procedure for summary judgment dismissing the first amended complaint (the "FAC") of lead plaintiff George Jenkins ("Lead Plaintiff" or "Jenkins"). Lead Plaintiff has presented no opposition to the Flamel Defendants' motion.

Upon the facts and conclusions set forth below, the motion is granted and the FAC is dismissed.

### **Prior Proceedings**

The facts underlying this action were previously set forth in a number of prior opinions and in the Flamel Defendants' Local Rule 56.1 Statement. See Billhofer v. Flamel Technologies, S.A., 07 Civ. 9920, 2010 WL 3703838 (S.D.N.Y. Sept. 21, 2010); Billhofer v. Flamel Technologies, S.A., 281 F.R.D. 150 (S.D.N.Y. 2012); Billhofer v. Flamel Technologies, S.A., No. 07 Civ. 9920, 2012 WL 30793186 (S.D.N.Y. July 30, 2012). Familiarity with the general background of this case is

assumed and facts relevant to the instant motion are summarized below.

The FAC in this putative class action was filed on March 27, 2008 and alleged securities fraud against Flamel and four of its principals. This action arose out of the March 2007 commercial launch of COREG CR, a drug developed by GlaxoSmithKline ("GSK"), which employed Flamel's "micropump" for drug delivery.

Flamel is a French company whose common stock traded as American Depositary Receipts ("ADRs") on the NASDAQ Stock Market ("NASDAQ"). Flamel's business focuses on drug delivery technologies which allows pharmaceutical companies to develop extended release versions of their medications. Willard serves as Flamel's Chief Executive Officer. (FAC ¶¶ 4-5, 13).

Flamel partnered with GSK to develop COREG CR, a medication for heart disease and hypertension patients, which was launched in March 2007. COREG CR was intended to supplant COREG IR, another medication GSK had developed but whose patent exclusivity was expiring in September 2007, exposing it to generic competition. The primary advantage of COREG CR over

COREG IR was that CR (for "controlled release") allowed for once daily dosages compared with IR (for "immediate release"), which requires twice daily dosages. (Id. ¶¶ 14-15).

The FAC alleged that COREG CR was Flamel's "lead product" whose success depended upon converting COREG IR patients to COREG CR prior to the expected entry of generic COREG IR competition in late 2007. (Id. ¶¶ 15-16). In addition, according to the Plaintiffs, the "primary selling point" for COREG CR was that its once-daily formulation represented an "improved and better version of COREG IR" because patient compliance with their medication is a "primary issue" for cardiac patients. (Id.).

The FAC alleged that the Defendants violated Sections 10(b) and 20(a) of the 1934 Securities Exchange Act by issuing misleading public statements between March 23, 2007 through August 22, 2007 in press releases, SEC filings and quarterly earnings conference calls, which, among other things, discussed the "success" of COREG CR (Id. ¶¶ 22-27). According to the Plaintiffs, these statements were misleading because the Defendants knew, but failed to disclose, the results of the

CASPER trial, which allegedly contradicted COREG CR's "primary selling point." (Id. ¶¶ 17-20).

The FAC claimed that, prior to March 23, 2007, Flamel learned the results of the CASPER trial, which showed that "switching from COREG IR to COREG CR was not associated with better drug taking compliance . . . ." (Id. ¶ 18-20). The CASPER trial results eventually became public on August 23, 2007 and the price of Flamel's ADRs "plummeted in response." (Id. ¶ 21.)

The Defendants moved to dismiss the FAC and the Honorable Charles S. Haight, Jr. denied that motion, holding that the facts pled were "more than sufficient to support an inference that Flamel knew something about the CASPER study results at some point during the 'Class Period.'" Billhofer v. Flamel Tech., SA, 663 F. Supp. 2d 288, 302 (S.D.N.Y. 2009). In addition, the Court held that Flamel's March 23 press release, which reported that COREG CR was a "success" and that "interest in [Flamel's] technologies has never been higher," was misleading because either (a) as of March 23, Flamel knew the CASPER trial results were not positive and thus knew that COREG CR was not a "success" and that GSK's "interest" in COREG CR

could not be "higher" or (b) Flamel later learned the CASPER trial results but failed to update its prior statement. Id. at 298-300. The action was transferred to this Court on October 5, 2009.

On April 29, 2010, the initial plaintiff, Christel Billhofer, moved to withdraw as lead plaintiff and substitute Jenkins. The Defendants opposed that motion on the grounds that document discovery obtained from non-parties demonstrated that Flamel was unaware of the CASPER trial results prior to their August 2007 publication and consequently the inference of scienter which the Court found had been raised in the FAC "can no longer be asserted in good faith." Billhofer v. Flamel Tech. SA, No. 07-9920, 2010 WL 3703838, at \*3 (S.D.N.Y. Sept. 21, 2010). The substitution motion was granted, holding, among other things, that "discovery is necessary to flush out what and when Flamel knew about the CASPER trial results." Id.

The parties engaged in extensive discovery for over one year until fact discovery was completed in November 2011. On January 22, 2010, the Lead Plaintiff filed a motion to certify this action as a class action and to be certified as

class representative. The Court granted that relief on March 15, 2012.

On December 15, 2011, after the close of discovery, Lead Plaintiff filed his responses to the Defendants' First Requests for Admission and moved to file a second amended class action complaint ("SAC"). Among the grounds stated for the motion were that discovery had revealed that the factual premise of the original complaint was incorrect and that the Lead Plaintiff wished to proceed on the basis of a new theory of the case.

On July 25, 2012, the Court denied Lead Plaintiff's motion to amend the FAC and file a SAC on futility grounds, stating that the Lead Plaintiff's new theory failed to state a claim and would be subject to a successful motion to dismiss. Billhofer, 2012 WL 30793186, at \*16.

Lead Plaintiff's counsel has subsequently informed the Flamel Defendants that they cannot, in good faith, oppose a motion for summary judgment on the FAC. Accordingly, the Flamel Defendants now move for summary judgment on the claims alleged

in the FAC. The motion was marked fully submitted on January 16, 2013.

### **The Summary Judgment Standard**

Summary judgment is granted only if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986); SCS Commc'ns, Inc. v. Herrick Co., 360 F.3d 329, 338 (2d Cir. 2004). In determining whether a genuine issue of material fact does exist, a court must resolve all ambiguities and draw all reasonable inferences against the moving party. See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986); Gibbs-Alfano v. Burton, 281 F.3d 12, 18 (2d Cir. 2002). In addition, courts do not try issues of fact on a motion for summary judgment, but rather, determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).



The moving party has the initial burden of showing that there are no material facts in dispute, Adickes v. S.H. Kress & Co., 398 U.S. 144, 157, 90 S. Ct. 1598, 26 L. Ed. 2d 142 (1970), and can discharge this burden by demonstrating that there is an absence of evidence to support the nonmoving party's case. Celotex, 477 U.S. at 325. The nonmoving party then must come forward with "specific facts showing that there is a genuine issue for trial," Fed. R. Civ. P. 56(e), as to every element "essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322. "[T]he non-moving party may not rely simply on conclusory allegations or speculation to avoid summary judgment, but instead must offer evidence to show that its version of the events is not wholly fanciful." Morris v. Lindau, 196 F.3d 102, 109 (2d Cir. 1999) (quotation omitted).

**The Flamel Defendants are Entitled to Judgment as a Matter of Law**

The linchpin of the FAC is that the Flamel Defendants knew that the results of the CASPER trial were not positive. (See FAC ¶¶ 17, 28). As Judge Haight noted in denying the motion to dismiss, the essence of the claim is that the Flamel

Defendants made positive statements relating to COREG CR's success while knowing that the results of the CASPER trial did not demonstrate improved compliance. Billhofer, 633 F. Supp. 2d at 299-200.

Here, it is undisputed that the Flamel Defendants did not know the results of the CASPER trial until the end of the class period. There are numerous documents which demonstrate that the Flamel Defendants did not know the results of the CASPER trial until the end of the class period. (See Edwards Decl. Exs. B-F). All of the witnesses who were questioned about this issue in their depositions also testified that the Flamel Defendants did not know about the CASPER trial results until the end of the class period. (Id. Exs. G-X).

Moreover, Lead Plaintiff has admitted that the Flamel Defendants did not know the results of the CASPER trial prior to August 20, 2007. (Id. Ex. A ¶¶ 2, 54-55). In the proposed SAC, Lead Plaintiff conceded that "Flamel had no role in the creation, funding, or support of the CASPER trial, and had no non-public information regarding the trial's outcome . . . ." (SAC ¶ 3). Indeed, Lead Plaintiff affirmatively stated that the Flamel Defendants were "completely unaware of the results" until

the end of the class period. (Id. ¶ 64); see also Billhofer, 2012 WL 3079186, at \*11 (stating that "[a]s the Plaintiff concedes, despite Willard having inquired about them, GSK never informed the Defendants about the CASPER trial results prior to late August 2007, and Willard honestly believed the CASPER trial would show positive results.").

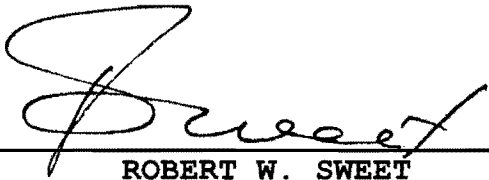
Accordingly, as there is no genuine issue of fact and no reasonable jury could find in the Lead Plaintiff's favor on his claim, the motion for summary judgment is granted. See Miner v. Clinton County, New York, 541 F.3d 464, 471 (2d Cir. 2008) (stating that "[a]n issue of fact is genuine if the evidence is such that a reasonable jury could have returned a verdict for the appellant.").

### **Conclusion**

Upon the facts and conclusions set forth above, the motion of the Flamel Defendants is granted, and the FAC of the Plaintiff will be dismissed with prejudice and costs.

It is so ordered.

New York, NY  
March 7, 2013



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ROBERT W. SWEET  
U.S.D.J.